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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/632,422	08/04/2000	Berton Gunter	MERK-0004/20671	1928

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EXAMINER
ZEMAN, MARY K

ART UNIT	PAPER NUMBER
1631	9

DATE MAILED: 07/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/632,422	GUNTER, BERTON	
	Examiner	Art Unit	
	Mary K Zeman	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *29 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-58* is/are pending in the application.

4a) Of the above claim(s) *10-58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1, 2 and 4-58 are pending in this application. Claims 10-58 have been withdrawn from consideration, and should be canceled. Claim 3 has been canceled. Claim 1 has been amended.

Applicant's arguments filed 4/29/2003 have been fully considered but they are not persuasive.

Rejections Maintained

Claims 1, 2 and 4-9 remain rejected under 103(a) as being unpatentable over the specification indicating all the algorithmic functions are known and used in the art under the name of S-PLUS by MATHSOFT.

Applicant's arguments have been fully considered, but are not persuasive. Applicant argues that the amended claims obviate this rejection, as the S-PLUS program is not concerned with any particular type of assay, or the identification of biological agents. This argument is not persuasive, as the new limitations in the claims do not require the performance of any particular assay, merely the generation of data resulting from said assays. This can be the retrieval of stored data. And, as previously set forth, the particular type of data analyzed by the known conventional software cannot make those known, conventional steps newly patentable. (In re Gulack) Applicant argues that the S-PLUS cannot correct the data, however, the correction is a mathematical function which can be performed by a computer, and as such is therefor disclosed.

As set forth previously, the specification identifies the MATHSOFT program S-PLUS, and notes that it allows for the analysis of raw data and offers the ability to transform that raw data according to the end use of the data. At page 12 of the specification, the following is set forth: "Commercially available statistical software may be employed to implement many of the functions of the algorithm of the present invention. Such software may for example include S-PLUS statistical data analysis software, produced and/or marketed by MATHSOFT, Inc. of Cambridge, Massachusetts... Examples of S-PLUS code written for the S-PLUS software and employed to implement the positionally correcting algorithm are set forth in the attached

appendix." This indicates that it is the commercially available and acknowledged prior art of the S-PLUS software that use used in the invention. The rejected claims do not require any new, novel or unobvious steps not set forth in the S-PLUS software. The specification and appendix merely choose various functions from known and commercially available software, and align them to perform a certain task. For example, at pages 14, lines 9-10, page 15, lines 4-5, and 25-27, page 16, lines 27-29, page17, lines 10-17, and page 18 lines 10-13, lines 17-30, (among others) the specification repeatedly points out that various features are either well known in the art, or provided by the S-PLUS software.

The difference between the prior art and the claimed invention of claims 2-5, and 7-9 is the recited data sources. These data sources are descriptive information stored on or employed by a machine. This information is fed into a known algorithm whose purpose is to compare or modify those data using a series of processing steps that do not impose a change on the processing steps and are thus nonfunctional descriptive material. The claimed invention uses known software to solve a known problem in a conventional manner. See pages 12-30 of the specification acknowledging known prior art computer assisted data analysis and modification techniques used in the methods set forth therein. Neither the specification, nor the claims set forth any special, non-obvious modifications to the known, conventional software and method steps. A method of using a known program (e.g. S-PLUS known in the prior art to MATHSOFT) for its known purpose to compare and modify data sets does not become non-obvious merely because new data becomes available for analysis. Nonfunctional descriptive material cannot render non-obvious an invention that would have otherwise been obvious. See In re Gulack, 703 F.2d 1381, 1385 (Fed. Cir. 1983) and MPEP 2106.

New Grounds of Rejection

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 2, 4-10 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to the manipulation of data, which method does not lead to the generation of a concrete tangible and useful result. At best, one identifies a data point. This data point, however, must be further manipulated and compared to be useful. *This is a new grounds of rejection necessitated by Applicant's amendments.* It is noted that the "generating" step added by the amendment is not actually limited to running a "wet" assay or actually running the screening assay. The generating step can be met by retrieving data from a data storage device. See MPEP 2106.

MPEP 2106: "For such subject matter to be statutory, the claimed process must be limited to a practical application of the abstract idea or mathematical algorithm in the technological arts. See Alappat, 33 F.3d at 1543, 31USPQ2d at 1556-57 (quoting Diamond v. Diehr, 450 U.S. at 192, 209 USPQ at 10). See also Alappat 33 F.3d at 1569, 31 USPQ2d at 1578-79 (Newman, J., concurring) ("unpatentability of the principle does not defeat patentability of its practical applications") (citing O 'Reilly v. Morse, 56 U.S. (15 How.) at 114-19). A claim is limited to a practical application when the method, as claimed, produces a concrete, tangible and useful result; i.e., the method recites a step or act of producing something that is concrete, tangible and useful. See AT &T, 172 F.3d at 1358, 50 USPQ2d at 1452. Likewise, a machine claim is statutory when the machine, as claimed, produces a concrete, tangible and useful result (as in State Street, 149 F.3d at 1373, 47 USPQ2d at 1601) and/or when a specific machine is being claimed (as in Alappat, 33 F.3d at 1544, 31 USPQ2d at 1557 (in banc)."

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028.

Official fax numbers for this Art Unit are: (703) 308-4242, (703) 872-9306. An *unofficial* fax number, direct to the Examiner is (703) 746 5279. Please call prior to use of this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the TC1600 Receptionist whose telephone number is (703) 308-0196.

mkz
7/2/03

MARY K. ZEMAN
PRIMARY EXAMINER
1631